



May 18, 2005

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Ortho Molecular Products Inc.  
3017 Business Park Drive  
P.O. Box 1060  
Stevens Point, WI 54481  
715.342.9881 Phone  
800.332.2351  
715.342.9866 Fax  
orthomolecularproducts.com

Office of Special Nutritional (HFS-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

**Name of Manufacturer:** Ortho Molecular Products, Inc.  
3017 Business Park Drive  
P.O. Box 1060  
Stevens Point, WI 54481

**Statement Text:** Premium Vascular Health, Cardiovascular Health

**Dietary Ingredients:** Plant Sterol Esters, Pantethine, EPA, DHA, Gelatin, Natural Mixed Tocopherols 90%, Natural vegetable capsules, Vegetable Glycerin, Purified Marine Triglyceride Concentrate, Purified Water.

**Dietary Supplement Name:** Triplichol

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

Melissa Slager  
Document Control / Training Manager  
Ortho Molecular Products

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### Attachment of Triplichol Labels

Suggested Use: As a dietary supplement, 2 packets per day with a meal or as recommended by your health care professional.

Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. This product contains the following potential allergen: Fish.

If you are pregnant or nursing, consult your physician before taking this product. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion. KEEP CONTAINER TIGHTLY CLOSED. STORE AT ROOM TEMPERATURE. KEEP OUT OF REACH OF CHILDREN. This product was sealed for your protection. Do not use if outer logoed neck seal or printed inner seal are missing or damaged.

Label ID L-OMP100-354060-B



Dietary Supplement Product #354



# Triplichol

## Premium Vascul

MOLECULAR  
PRODUCTS  
Matters®

**Triplichol™**  
**Heart Health Pack**

*"Products containing at least 0.65 g per serving of plant sterol esters, taken twice daily with meals for a daily total intake of at least 1.3 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease."*

*"Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of Triplichol provides 1.44 grams of EPA and DHA omega-3 fatty acids."*

### Supplement Facts

Serving Size 2 Packets  
Servings Per Container: 30

	Amount Per Serving	% Daily Value
2 packets contain		
Total Calories	13.14	
Calories from Fat	13.14	
Total Fat	1.46 g	2.24%*
Plant Sterol Esters	1.3 g	**
Paritethine	900 mg	**
EPA	840 mg	**
DHA	600 mg	**

\* % Daily Values are based on 2,000 calorie diet.  
\*\* % Daily Value not established

Other Ingredients: Gelatin, Natural Mixed Tocopherols 90%, Natural Vegetable Capsules, Vegetable Glycerin, Purified Marine Triglyceride Concentrate and Purified Water.

†These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Mfg. by: Ortho Molecular Products, Inc.  
3017 Business Park Drive Stevens Point, WI 54481

[OrthoMolecularProducts.com](http://OrthoMolecularProducts.com)